

Docket No.: VALTX.001A
Appl. No.: 10/698,148
Filing Date: October 31, 2003

Customer No.: 20995

REPLY BRIEF

Applicant	: Kagan et al.
App. No	: 10/698,148
Filed	: October 31, 2003
For	: APPARATUS AND METHODS FOR TREATMENT OF MORBID OBESITY
Examiner	: Phillip A. Gray
Art Unit	: 3767

Mail Stop Appeal Brief-Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief is responsive to the Examiner's Answer dated November 12, 2010. The arguments and responses presented in this Reply Brief supplement those presented in the Amended Appeal Brief filed on August 26, 2010 (the "Amended Appeal Brief"), all of which are incorporated by reference herein.

As a preliminary matter, the claim rejections under 35 U.S.C. §103 extending from page 3 to page 9 of the Examiner's Answer appears to be substantially identical to the grounds for rejection set forth in the Final Office Action mailed on July 9, 2009. Because the Amended Appeal Brief already fully address the issues raised in this section, this Reply Brief only responds to issues raised in the "Response to Argument" section beginning at page 9. By declining to address certain comments made in the "Response to Argument" section, or other sections in the Examiner's Answer, Appellants do not imply agreement with any such comments. Rather, Appellants rely on the arguments as originally presented in the Amended Appeal Brief with respect to any arguments in the Examiner's Answer not specifically addressed herein.

I. STATUS OF CLAIMS

Claims 43-50, 52, 54-61, and 72-73 are currently pending. Claims 1-42, 51, and 53 have been cancelled. Claims 62-71 and 74-75 are withdrawn. Claims 43-50, 52, 54-61, and 72-73 stand rejected, and are the subject of this Appeal. Claim 43 is the sole pending independent claim.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 43-50, 52, 54-61, and 72-73 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pub. No. 2004/0039452 A1 to Bessler in view of U.S. Pat. No. 6,254,642 to Taylor, and further in view of U.S. Pat. No. 5,470,337 to Moss. The aforementioned claims also stand rejected in view of U.S. Pub. No. 2004/0082963 A1 to Gannoe et al. in view of Taylor, and further in view of Moss. Claim 52 is also rejected as unpatentable over Bessler in view of Taylor in further view of Moss or Gannoe in view of Taylor in further view of Moss.

III. ARGUMENT

In the Amended Appeal Brief, Appellants submitted that the rejection of Claims 43-50, 52, 54-61, and 72-73 is improper because the Examiner has not established a *prima facie* case of obviousness as required by 35 U.S.C. § 103(a). Furthermore, Appellants argued that secondary factors, including unexpected results, failure of others, and teaching away necessitate a finding of nonobviousness. In the discussion below, Appellants respond to various points raised by the Examiner in the Examiner's Answer in response to the Amended Appeal Brief. With regard to any of the Examiner's arguments in the Answer that may not be specifically addressed in the Reply Brief herein, Appellants do not acquiesce. Rather, for purposes of brevity Appellants refer back to the arguments as presented in their Amended Appeal Brief and incorporate that Brief in its entirety by reference herein.

A. Claims 43-50, 52, 54-61 and 72-73 Would Not have been Obvious over Bessler or Gannoe in view of Taylor, and further in view of Moss.

1. One of Ordinary Skill Would Have No Reason to Combine the References

In the Examiner's Answer, the Examiner acknowledged that "Gannoe and Bessler each teach an alternate means of attaching a sleeve to the GEJ area (Gannoe by serosal to serosal fold and Bessler by expand[a]ble stent)" and these attachments are distinct from "going through the tissue directly as taught by Taylor."¹ The Examiner alleged in the Answer that one of ordinary skill in the art would have a reason to modify the primary references because a Taylor or Moss-type penetrating attachment would "provide (and one would expect) a more stable and permanent 'attachment' or fixing of the device to the patient at the GEJ."² Furthermore, the Examiner noted that "Taylor's [and Moss's] attachment is consistent with the operation and function of the attachments of Gannoe or Bessler."³

Appellants disagree that one of ordinary skill in the art would find that a Taylor or Moss-type attachment would be more stable than that disclosed in either Bessler or Gannoe, as the Examiner has not cited any factual basis either in the references or elsewhere for this assertion. Furthermore, Appellants note that contrary to the Examiner's assertion, a Taylor or Moss-type attachment functions very differently from those of Bessler and Gannoe, as discussed in detail in the Amended Appeal Brief and briefly reiterated below, and that those profound differences would not provide one of ordinary skill in the art with a reason to combine the cited references in the manner claimed.

a. Bessler

Appellants reiterate that the Examiner must consider Bessler in its entirety including its particular non-penetrating anchoring system that leads away from the claimed invention.⁴ As

¹ Examiner's Answer filed November 12, 2010 at p. 10.

² *Id.* at pp. 10-11.

³ *Id.* at pp. 11.

⁴ *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); M.P.E.P. § 2142.01 (VI); *KSR International v. Teleflex*, 550 U.S. 398, 418 (2007).

such, when attempting to make a combination, the Examiner cannot merely pick out the tubular member of Bessler and ignore the non-penetrating manner in which the Bessler tubular member is attached. Combining Bessler's tubular member with the penetrating attachment mechanisms taught in Taylor and further modified by Moss to come up with the invention as claimed is wholly improper.⁵ Thus, Appellants submit that the Examiner has failed to provide a cognizable reason to combine the references.

As noted, in the course of distinguishing the prior art, Bessler at ¶ [0005] explained: "There has been, and continues to be, a need for less traumatic surgical or non-surgical techniques to treat obesity." [emphasis added]. Bessler's exclusive use of a nonpuncturing fixation was therefore a well-considered aspect of his design, and consistent with a general trend in medicine to seek out less invasive procedures. By the time of Bessler's filing date, persons of ordinary skill in the medical device arts were familiar with a wide variety of invasive tissue engaging attachment structures such as staples, sutures, and barbs.⁶ Yet Bessler failed to disclose even a single puncturing attachment structure, signaling in the context of Bessler's disclosure a clear preference for nonpuncturing attachment.

Taylor fails to cure the deficiency in the teachings of Bessler. The use of sharpened barbs as disclosed in Taylor are therefore inconsistent with Bessler's apparent intent of providing a non-penetrating less traumatic device for gastric bypass. Thus, even disregarding the different intended use in Taylor of treating GERD, the addition of an invasive attachment structure in the context of Bessler's nonpuncturing attachment fails to establish a *prima facie* case.

Even assuming the combination of the barbed spikes of Taylor with the bypass structure of Bessler were a proper combination, it would still fail to yield a *prima facie* showing of obviousness. Recognizing this deficiency, the Examiner has relied upon a further combination with Moss. A person of ordinary skill in the art attempting to practice the invention of Bessler would have no reason to include a penetrating fastener of the type disclosed in Moss any more than a penetrating fastener of the type disclosed in Taylor. Appellants respectfully submit that one of skill in the art would have absolutely no reason to add the penetrating attachment anchors

⁵ See *id.*

of Moss which are movable from a reduced cross section to an enlarged cross section to the disclosure of Bessler, and that one of ordinary skill in the art would not at all find all attachments to be interchangeable.⁷

b. Gannoe

The Examiner alleged in the Answer that one of ordinary skill in the art would modify Gannoe in the direction of Taylor and Moss because the attachment of Taylor or Moss is more stable and permanent than the tissue bond of Gannoe.⁸ Appellants disagree, and reiterate that Gannoe's plication results in a permanent serosa to serosa scar tissue bond to reinforce and hold a tissue plication in place that, contrary to the Examiner's assertion, is more permanent than Appellants' attachment method as claimed. Thus, Applicants respectfully submit that the sole reason advanced by the Examiner for combining the cited references is not correct, and as such no *prima facie* case of obviousness exists. Because, among other things, Gannoe's serosa to serosa bond is permanent without surgical or other invasive intervention, Appellants have specifically avoided this approach and have expressly excluded this from the present claims. As noted above, Appellants submit that the Examiner must consider the primary reference cited as the basis for the rejection, Gannoe, in its entirety, including its particular plication anchoring system that leads away from the claimed invention.⁹ As such, when attempting to make a combination, the Examiner cannot merely pick out Gannoe's sleeve while ignoring the permanently tissue altering plication anchoring system. It would be wholly improper to combine Gannoe's sleeve with the particular attachment mechanisms taught in Taylor and further modified by Moss to come up with the invention as claimed.¹⁰ Thus, Appellants submit that the Examiner has still failed to provide a cognizable reason to combine the references.

⁶ See, e.g., Taylor at col. 1, lines 61-63; col. 3 line 47 – col. 4 line 13; col. 4 lines 38-46.

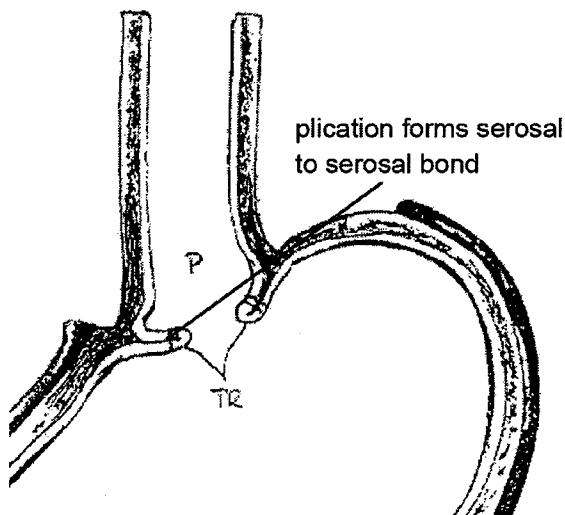
⁷ 37 C.F.R. § 1.132 Declaration of Christopher Thompson, M.D. filed on November 21, 2008 at para. 9 (hereinafter "Thompson Declaration").

⁸ Examiner's Answer at pp. 10-11.

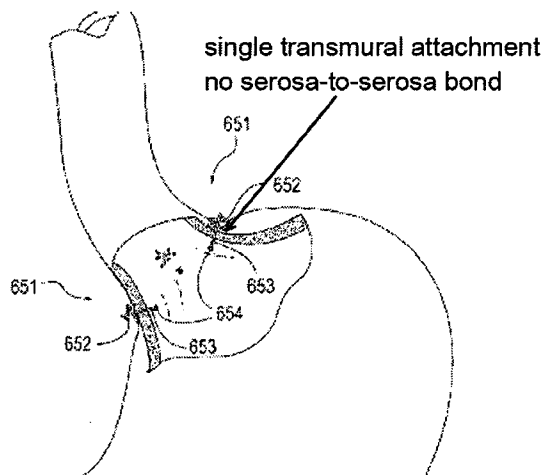
⁹ *W.L. Gore*, 721 F.2d at 1550; M.P.E.P. § 2142.01 (VI).

¹⁰ See *id.*

Furthermore, Appellant submits that the Examiner's Answer has failed to address the Appellant's argument as stated in the Amended Appeal Brief that even assuming for the sake of argument that Gannoe, Taylor, and Moss are combinable, a combination of Gannoe, Taylor, and Moss would result in a gastric bypass stent wherein a penetrating attachment is driven through a mucosal-to-mucosal plication as taught by Gannoe. Such a combination will still facilitate serosal to serosal bonding via the plication, contrary to the recitation of Claim 43 of "attaching the proximal end [of the gastrointestinal sleeve] at the attachment site without creating a serosal to serosal bond." The Examiner has simply failed to identify how the proposed combination would create an attachment without creating a serosal to serosal bond as claimed. Since the combination of references fails to teach or suggest each and every claim element, the Examiner has not made a *prima facie* case of obviousness. Furthermore, further modifying the combination (i.e., removing Gannoe's serosal to serosal bond for attachment) would destroy the purpose of Gannoe's device and act as a substantial disincentive for the proposed combination.¹¹



Gannoe



Embodiment of claimed method

¹¹ See M.P.E.P. § 2143.01(V).

2. One of Ordinary Skill Would Have No Reasonable Expectation of Success in the Combination

The Examiner merely alleged in the Answer that Taylor appears to show connection of a tube sleeve near the GEJ of a patient using a barbed attachment, and that because the Taylor tube sleeve is similar in form and structure to the attachments of Bessler and Gannoe, a reasonable expectation of success in the combination exists.¹² Appellants continue to disagree, and submit that this unsupported rationale fails to rebut Appellant's evidence as noted in multiple responses of record and the Thompson Declaration. As discussed, *inter alia* in the Amended Appeal Brief, prior to the present invention, to Appellants' knowledge, all methods of attaching a device to an attachment site near or at the gastroesophageal junction with the exception perhaps of esophageal stents in certain cancer patients, have generally resulted in failure.¹³ As such, no reasonable expectation of success in the combination exists. *See also* the discussion of failure of others at Section 3(b) of the Amended Appeal Brief.

3. Secondary Considerations Support a Finding of Non-Obviousness

a. Teaching Away

The Examiner noted in the Answer that "simply that there are differences between two references is insufficient to establish that such references 'teach away' from any combination thereof."¹⁴ Appellants submit that they have not only pointed out the substantial differences among the cited references that render the references not properly combinable, but have also affirmatively provided ample evidence that one of ordinary skill in the art would be lead away from the invention as claimed, as required to show a teaching away.¹⁵

With respect to Bessler, Bessler discloses that his device is advantageous as less traumatic than previous surgical techniques.¹⁶ All disclosed embodiments of Bessler's device,

¹² Examiner's Answer at p. 11.

¹³ *See* Thompson Declaration at para. 9.

¹⁴ Examiner's Answer at pp. 11-12.

¹⁵ *W.L. Gore*, 721 F.2d at 1550; M.P.E.P. § 2142.01 (VI).

¹⁶ Bessler at paragraph [0005].

involve an expandable stent 4¹⁷ that does not penetrate any tissue walls to meet its objective of securing the ends of the device within the esophagus. In general, the teachings of Bessler would lead one of skill in the art in the direction of a non-penetrating anchoring system, such as a balloon expandable or self expanding stent as disclosed therein. Thus, Bessler tends to teach away from the use of a penetrating tissue attachment, and that the use of Taylor or Moss's penetrating tissue fastener to secure Bessler's bypass stent would be contrary to Bessler's intent of providing a less traumatic device for gastric bypass.¹⁸

With respect to Gannoe, Gannoe teaches a mucosal to mucosal puncture of a plication, for the purpose of both reducing the diameter of the opening at the base of the esophagus and to permit serosa to serosa bonding to enable a lasting clinical result. This disclosure would not give one of ordinary skill in the art any reason to eliminate the plication which is of central importance to Gannoe and accordingly contained in every embodiment disclosed in Gannoe. As noted above, the Examiner must take into account the Gannoe reference as a whole, and it is not permissible to conveniently ignore the plication feature when attempting to combine references.¹⁹ Gannoe's objective of obtaining permanent serosa to serosa healing thus at least implicitly teaches away from the invention as claimed, which excludes serosa to serosa bonding as recited in Claim 43.²⁰ In general, the teachings of Gannoe would lead one of skill in the art in the direction of creating a plication for serosal-to-serosal bonding for permanent healing. Thus, Appellants submit that Gannoe tends to teach away from the use of Appellants' claimed transmural tissue attachment, which pursues the opposite objective of achieving attachment while leaving the native anatomy intact. Furthermore the use of Taylor's spikes through a non-plicated tissue wall to secure Gannoe's sleeve device would be contrary to Gannoe's intent of providing a plication for permanent serosa-to-serosa bonding. *See id.*

¹⁷ *Id.* at Fig. 1.

¹⁸ *See* Thompson Declaration at para. 7.

¹⁹ *See W.L. Gore*, 721 F.2d at 1550.

²⁰ *See* Thompson Declaration at para. 8.

B. The Examiner Must Give Proper Weight to the Thompson Declaration

The Examiner noted in the Answer that Thompson Declaration of record was not entitled to sufficient weight as mere “opinion evidence,” and “statements of why ‘he’ would or wouldn’t do something but gives little facts and standards as to what is the level of skill in the industry at the time of the invention.”²¹ Appellants continue to disagree, and reiterate that opinions introduced on the issue of the level of ordinary skill are usually determined by reference to the subjective reaction of persons so skilled, and even assuming for the sake of argument that a *prima facie* case of obviousness has been established, opinion evidence of one of ordinary skill in the art based on information uniquely within their competence bearing on the level of ordinary skill in the art at the time the invention was made can overcome a *prima facie* case of obviousness.²²

Similar to the *Oelrich* and *Meng* cases cited above, in which opinion affidavits of one of ordinary skill in the art regarding the level of skill in the art was considered dispositive in finding that a claimed invention was nonobvious, the Thompson Declaration was also introduced on the issue of the level of ordinary skill, and as such should be entitled to considerable weight. Dr. Thompson was a physician in the art at the time the invention was made who has substantial clinical and research experience in gastrointestinal procedures that are the subject of the claimed invention.²³ The Thompson Declaration opines on the art cited as a basis for an obviousness rejection by the Examiner based on Dr. Thompson’s knowledge, clinical, and research experience that is uniquely within his competence, and clearly states reasons why he would see no reason to combine the cited references to come up with the claimed invention, why he would not have expected the invention to have a reasonable expectation of success, and how the claimed invention produced unexpected results.²⁴ As such, Appellants submit that the Thompson Declaration is compelling evidence of nonobviousness of record on the issue of the level of

²¹ Examiner’s Answer at p. 12.

²² *In re Oelrich*, 579 F.2d 86, 91 (C.C.P.A. 1978); *In re Meng*, 492 F.2d 843, 848-849 (C.C.P.A. 1974)

²³ Thompson Declaration at paras. 1-3.

²⁴ *Id.* at paras. 7-9.

ordinary skill.²⁵ Thus, Appellants respectfully request that the Board consider the Declaration, and afford it considerable weight in view of the relevant case law and M.P.E.P. sections cited above.

IV. CONCLUSION

In summary, the references cannot be reasonably combined because the prior art does not provide any reason to make the cited combination, especially when the prior art references are properly considered as a whole, including portions that may teach away from the invention as claimed. Moreover, certain combinations cited by the Examiner, even when combined, do not disclose all claimed elements. Furthermore, the references do not provide a reasonable expectation of success in such a combination. As a result, the Examiner has not made a *prima facie* case of obviousness. However, even assuming *arguendo* that the Examiner has established a *prima facie* case of obviousness, secondary factors, including unexpected results and long felt need, necessitate a finding of nonobviousness. In addition, while independent Claim 43 is being specifically argued in the present appeal, Appellants note that dependent Claims 44-50, 52, 54-61, 72-73, as well as withdrawn claims 62-71 and 74-75 incorporate all the elements of the independent claims. Therefore these dependent and withdrawn claims are nonobvious for at least the reasons discussed above, and Appellants request that the withdrawn claims be reinstated into the application should Claim 43 be found allowable.

²⁵ See M.P.E.P. § 2143.01 (III); *Oelrich*, 579 F.2d at 91; *Meng*, 492 F.2d at 848-849.

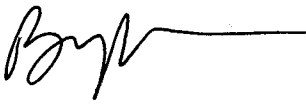
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Respectfully submitted,

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Dated: 1/10/11

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